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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/775,677 | 02/05/2001 | Jan Otto Solem | JM-050 CIP | 3473 |

7590

02/08/2005

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IRVINE, CA 92614

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| EXAMINER |
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CHATTOPADHYAY, URMI

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3738

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,677

Applicant(s)

SOLEM ET AL. 

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 22, 25-27, 30, 32-40 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 25-27, 32-36 and 74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 is/are allowed.
- 6) ☒ Claim(s) 22, 30 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 12/29/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/775,677 is acceptable and a RCE has been established. An action on the RCE follows.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/29/04 has been entered. The references cited therein have been considered by the examiner. An initialed and signed copy of the PTO-1449 is enclosed.

Allowable Subject Matter

3. The indicated allowability of at least claims 22, 30 and 37-40 is withdrawn in view of the newly discovered reference(s) to Buchanan et al. (*Circumferential Suture of the Mitral Annulus for Correction of Mitral Regurgitation in Dogs*). Rejections based on the newly cited reference(s) follow.
4. Claims 14-17 are allowed.

Election/Restrictions

5. Because independent claims 22 and 38 are rejected by prior art, the Election/Restriction set forth in the office action mailed 5/6/02 is reinstated. Applicant had elected Group I, Species

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9 (Figures 19-20) in Paper No. 9 filed on 8/6/02. Therefore, claims 25-27, 32-36 and 74 are again withdrawn from further consideration for being drawn to a non-elected species. The claims currently pending are claims 14-17, 22, 25-27, 30, 32-40 and 74. The claims being considered for further examination on the merits are claims 14-17, 22, 30 and 37-40.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 22, 30 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchanan et al. (*Circumferential Suture of the Mitral Annulus for Correction of Mitral Regurgitation in Dogs*).

Buchanan et al. discloses a medical device and system for remodeling an extravascular tissue structure adjacent to a vessel in a patient with all the elements of claims 22, 38 and 40. See Figures 2 and 5, “Objective”, “Methods” and “Clinical Relevance” on page 182, and “PSS Tightening” on pages 185-186 for a medical device comprising an elongate body (purse-string suture PSS) extending between a proximal end and distal end. The elongate body (PSS) is adjustable between a first configuration having a first shape such that the elongate body is adapted to be delivered *at least in part* into the coronary sinus (Figure 2) and a second configuration having a second shape such that the elongate body is adapted to exert a force from within the coronary sinus (Figure 5) onto the mitral valve annulus in order to remodel the mitral

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valve annulus. See Figure 2 and “Guidewire and Catheter Insertion” and “PSS Passage Through the Right Atrium” on pages 184-185 for a deployment system (guide catheter and 46 cm straight guidewire) cooperating with the elongate body (PSS) and being adapted to at least in part deliver the elongate body (PSS) in the first configuration at least in part into the coronary sinus.

Claim 30, see Figure 5. Because the elongate body (PSS) in the second configuration is in the form of a loop, the elongate body at least in part within the coronary sinus defines an arc.

Claim 37, see Figure 5, “Clinical Relevance” on page 182 and “PSS Tightening” on pages 185-186 for adjusting the elongate body (PSS) from the first configuration to the second configuration within the coronary sinus to compress the mitral valve annulus to reduce the diameter of the space defined thereby.

Claim 39, see column 2, lines 23-26 and “PSS Passage Through the Right Atrium” on page 184 for the deployment system comprising a delivery member (46 cm straight guidewire) coupled to the elongate body (PSS) and adapted to advance the elongate body (PSS) into the coronary sinus.

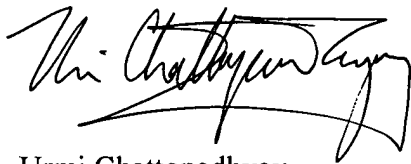
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748.

The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

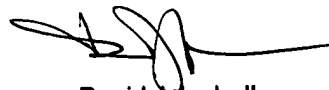
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner